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15 JUL 2004

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07 / 00048

SCHWEIZERISCHE EIDGENOSSENSCHAFT
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Attestation

Les documents ci-joints sont conformes aux pièces originales relative à la demande de brevet spécifiée aux pages suivantes, déposées auprès de l'Office soussigné, en tant qu'Office récepteur au sens de l'article 10 du Traité de coopération en matière de brevets (PCT).

Confirmation

It is hereby confirmed that the attached documents are corresponding with the original pages of the international application, as identified on the following pages, filed under Article 10 of the Patent Cooperation Treaty (PCT) at the receiving office named below.

Bern, 23. Januar 2003

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Patentverfahren
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Rolf Hofstetter

PCT REQUEST

Original (for SUBMISSION) - printed on 28.01.2002 10:19:13 AM

0	For receiving Office use only	
0-1	International Application No.	PCT/CH 02 / 00046
0-2	International Filing Date	28. Jan. 2002 (28.01.02)
0-3	Name of receiving Office and "PCT International Application"	RO / CH - Demande internationale PCT
0-4	Form - PCT/RO/101 PCT Request	
0-4-1	Prepared using	PCT-EASY Version 2.92 (updated 01.01.2002)
0-5	Petition The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	Receiving Office (specified by the applicant)	Swiss Federal Intellectual Property Institute (RO/CH)
0-7	Applicant's or agent's file reference	147-7.B.WO
I	Title of invention	PERITONEAL DIALYSIS SYSTEM
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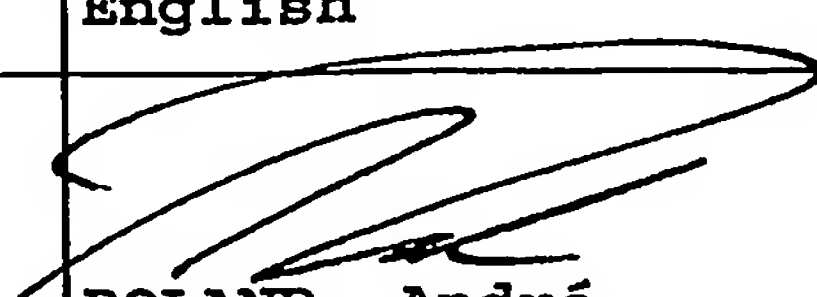
Original (for SUBMISSION) - printed on 28.01.2002 10:19:13 AM

IV-1	Agent or common representative; or address for correspondence The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:	agent
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V	Designation of States	
V-1	Regional Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	<p>AP: GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW and any other State which is a Contracting State of the Harare Protocol and of the PCT</p> <p>EA: AM AZ BY KG KZ MD RU TJ TM and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT</p> <p>EP: AT BE CH&LI CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR and any other State which is a Contracting State of the European Patent Convention and of the PCT</p> <p>OA: BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG and any other State which is a member State of OAPI and a Contracting State of the PCT</p>
V-2	National Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	<p>AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH&LI CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG US UZ VN YU ZA ZM ZW</p>

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147-7.B.WO

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V-5	Precautionary Designation Statement In addition to the designations made under Items V-1, V-2 and V-3, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except any designation(s) of the State(s) indicated under item V-6 below. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit.		
V-6	Exclusion(s) from precautionary designations	NONE	
VI	Priority claim	NONE	
VII-1	International Searching Authority Chosen	European Patent Office (EPO) (ISA/EP)	
VIII	Declarations	Number of declarations	
VIII-1	Declaration as to the identity of the inventor	-	
VIII-2	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	-	
VIII-3	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	-	
VIII-4	Declaration of inventorship (only for the purposes of the designation of the United States of America)	-	
VIII-5	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	-	
IX	Check list	number of sheets	electronic file(s) attached
IX-1	Request (including declaration sheets)	4	-
IX-2	Description	8	-
IX-3	Claims	5	-
IX-4	Abstract	1	EZABST00.TXT
IX-5	Drawings	2	-
IX-7	TOTAL	20	
	Accompanying items	paper document(s) attached	electronic file(s) attached
IX-8	Fee calculation sheet	✓	-
IX-17	PCT-EASY diskette	-	Diskette
IX-19	Figure of the drawings which should accompany the abstract	1	
IX-20	Language of filing of the international application	English	
X-1	Signature of applicant, agent or common representative		
X-1-1	Name (LAST, First)	ROLAND, André	

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10-1	Date of actual receipt of the purported international application	28. Jan. 2002 (28.01.02)
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PCT REQUEST

Original (for SUBMISSION) - printed on 28.01.2002 10:19:13 AM

10-2	Drawings:	
10-2-1	Received	
10-2-2	Not received	
10-3	Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application	
10-4	Date of timely receipt of the required corrections under PCT Article 11(2)	
10-5	International Searching Authority	ISA/EP
10-6	Transmittal of search copy delayed until search fee is paid	X

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11-1	Date of receipt of the record copy by the International Bureau	
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Peritoneal dialysis system

The present invention relates to a peritoneal dialysis sampling system to be used in a peritoneal dialysis system which is programmed to deliver fluid to a peritoneal cavity of a patient and to drain the fluid from the cavity, said peritoneal dialysis system comprising a supplying line and supplying means for supplying dialysis fluid to the peritoneal cavity, a draining line and draining means for draining the fluid from the cavity.

15 Different tests have been proposed to evaluate the patient membrane characteristics in order to improve the exchanges of fluid during peritoneal dialysis according to each patient. For instance the PDC test according to Haraldsson and Rippe, based on the three pore model, is commonly used to achieve this objective. Other tests would also be of interest if they would be able to evaluate the specific outcome of a given peritoneal dialysis type of cycles for a given patient and be used to improve those cycles based on the peritoneal dialysis outcome.

25 However all present tests show some inconvenients and limitations. In particular they cannot be reliable enough due to the impossibility of carrying out measurements during certain periods such as dwell time. Those tests are also not able to directly evaluate the outcome of a given type of cycle but rather evaluate the membrane characteristics in order to calculate optimized cycles for the patient. With the PDC test for example, there must be a full exchange cycle before carrying the measurements on the drained volume. State of the art tests also not allow the automatic use of different liquids and/or different concentrations, nor the automatic sampling.

35 Furthermore they are particularly cumbersome for the patient since they have to be manually done over a 24h period of time, with typically 5 exchanges. Therefore, the use of those tests is today limited to certain patients and require specific conditions to be conducted.

5 One of the object of the present invention is to avoid the previous listed problems.

It relates to a peritoneal dialysis sampling system to be used in a peritoneal dialysis system which is programmed to deliver fluid to a peritoneal cavity of a patient and to drain the fluid from the cavity, said peritoneal dialysis system
10 comprising a supplying line and supplying means for supplying dialysis fluid to the peritoneal cavity, a draining line and draining means for draining the fluid from the cavity, said peritoneal dialysis sampling system being characterized by the fact that it consists of an automatic sampling system which is able to automatically sample volumic fractions of the dialysate contained in the peritoneum of the
15 patient at specific time intervals in order to evaluate the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a given patient.

The automatic sampling system is connected on the draining line either between the patient peritoneum and the draining means or between the draining means
20 and a waste collector.

Connecting the automatic sampling system according to the invention on the draining line allows to carry out a test at any time by drawing liquid directly from the peritoneum. It also allows to take samples of fluid at different points of time
25 and having different sample volumes during the same cycle. All these possibilities improve considerably the evaluation of the peritoneal membrane characteristics and/or the peritoneal dialysis outcome for a given patient.

In particular, the possibility to increase the number of sampling steps and
30 automatically vary the dialysate volume and concentration over a certain period of time allows to increase the number of information collected over a limited period of time. As a result, a full and more detailed patient peritoneal membrane evaluation can be made over a shorter period of time, allowing such evaluation to be conducted automatically preferably overnight. In certain circumstances, it may
35 be useful to add one or several more manual samplings over the day, although the more detailed information would have been collected over the night by use of the automatic sampling system according to the present invention.

5

Preferably the automatic peritoneal dialysis sampling system is provided with means for defining the specific time intervals for sampling volumic fractions in relation with the peritoneal dialysis program sequences.

- 10 The evaluation of the peritoneal membrane characteristics may be improved by providing the automatic peritoneal dialysis sampling system with means, e.g. a system of valves and separate fluidic paths, in order to sample different peritoneal dialysis fractions and collect them in separate containers for a later detailed analysis of their specific content.

15

The automatic peritoneal dialysis sampling system may be connected between the patient peritoneum and the draining means, requiring sampling means to sample liquid from the peritoneum at different points of time. The sampling means may, for example, be of a peristaltic type allowing a precise volumic sampling.

- 20 Alternatively, the sampling means may result from vacuum originating from the sampling containers which may be controlled by a series of valves, or by gravity. In another embodiment of the present invention the automatic peritoneal dialysis sampling system may be connected after the draining means, such draining means being used, in such case, for both draining the dialysis fluid after each cycle as well as collecting the sampling fractions. In the event of dwell time sampling, the draining means would be activated to sample the volumic fraction required during dwell time, while in the drain phase of each cycle only a fraction of the drainage volume would be collected by use, for example, of a valve system.

- 30 The connection of the automatic peritoneal dialysis sampling system to the draining line may also be made by an electromechanical valve which is actuated in relation with a specific functioning of the draining means.

- 35 When the connection of the automatic peritoneal dialysis sampling system to the draining line is situated between the patient peritoneum and the draining means, the automatic sampling can be made during the dwell time of the peritoneal dialysis cycle and/or during the drain cycle without interfering with the peritoneal

5 dialysis system. When the connection of the automatic peritoneal dialysis
sampling system is situated after the draining means, the automatic sampling can
only occur during the drain phase of each cycle or, alternatively, can also occur
during the dwell time provided the draining means are activated during such dwell
time for that purpose. In the first case, the automatic peritoneal sampling system
10 requires sampling means, while in the latest case the draining means of the
peritoneal dialysis system are also used for sampling purposes.

The sampling means, if required, preferably include pumping means such as a
peristaltic pump. They may also be of a gravity type, or vacuum type, if in
15 connection with a series of valves.

In a preferred embodiment the automatic sampling system comprises a series of
sampling containers, pumping means and a series of valves in order to direct a
certain quantity of each fluid sample to a given sampling container.

20

The sampling containers may consist of soft pouches.

The automatic sampling system may be composed of a series of valves which are
controlled by an electronic system in order to direct a certain quantity of each fluid
25 sample to a specific sampling container. The valves may be of electromagnetic
type.

Preferably the automatic sampling system comprises means for eliminating a
volume of liquid between two samplings at least equivalent to the dead volume
30 contained between the patient and the sampling level. This can be done by
providing the system with a purging line. With such a configuration, after a first
sampling, the draining line is connected to the purging line in order to purge the
above cited dead volume in order to prevent mixing of two different samples. A
second sampling occurs then when the draining line is connected to another
35 sampling container. Purging can be obtained either by use of the sampling means
or, in the configuration with draining means from the automatic peritoneal dialysis
system, by use of such draining means.

5

Advantageously, both systems: the peritoneal dialysis system which comprises an automatic peritoneal dialysis exchange system, and the automatic peritoneal dialysis sampling system are connected to the patient peritoneum and comprise means for exchanging information together in order for the automatic peritoneal dialysis sampling system to determine the appropriate timing for each sampling on the basis of the dialysis exchange cycles of the automatic peritoneal dialysis exchange system.

In a further embodiment, the automatic sampling system under the present invention can also be used to not only determine the membrane characteristics but also evaluate one or several peritoneal dialysis exchange cycles in order to determine the best appropriate exchange cycle or series of cycles for the patient.

In a preferred embodiment both automatic peritoneal dialysis sampling system and automatic peritoneal dialysis exchange system are similar systems which are synchronized and which are working with different software and fluidic connections. For instance, they both may comprise peristaltic pumps.

In another preferred embodiment of the present invention, the automatic peritoneal dialysis sampling system only consist of a series of electro-valves and containers, which electro-valves are controlled by the automatic peritoneal dialysis system. In such preferred embodiment, the sampling is directed from the peritoneum to the containers by use of the drawing means of the automatic peritoneal dialysis system which contains a specific order of sequence for the opening and closing of specific valves in connection with the peritoneal dialysis cycles.

The peritoneal dialysis system may comprise a memory key which contains all the necessary data to program the functioning of said automatic peritoneal dialysis sampling system according to the peritoneal dialysis cycles and to store the sampling information.

5 The automatic peritoneal dialysis sampling system may comprise means for sequentially collecting sample volumes in a tubing, each sample being separated from the previous one by an air bubble inserted by the automatic peritoneal sampling system in-between each sample.

10 In order to store the samples in optimal conditions until analysis the sampling containers may preferably be enclosed inside a cooling box which comprises cooling means.

Advantageously the automatic peritoneal dialysis sampling system comprises
15 analyzing means for directly analyzing of at least one characteristic of the sample in-line, such as by spectroscopy, fluorometry or by use of chemical or electro-chemical means.

The automatic sampling system may be adapted to measure different
20 constituents/parameters such as glucose, urea, creatinine, sodium, chloride, albumine, proteins, osmolarity or ph.

For instance the result of the in-line analysis is used to optimize the next peritoneal dialysis exchange cycle or sampling intervals in order to improve the
25 membrane characteristics evaluation or directly evaluate the impact of specific changes on the peritoneal dialysis outcome for the patient.

30

35 Some embodiments of the invention will be discussed hereafter in a more detailed way.

5 Figure 1 illustrates a first embodiment of the system according to the invention where the automatic sampling system is connected on the draining line between the patient peritoneum and the draining means.

10 Figure 2 illustrates another embodiment of the system according to the invention where the automatic sampling system is connected on the draining line between the draining means and a waste collector.

The peritoneal dialysis system according to figure 1 consists of a first system 1 comprising a first peristaltic pump 3, dialysis fluid containers 4, a line 6,7
15 consisting of a supplying/draining line 7 which is arranged between a patient 5 and the first peristaltic pump 3 and a draining line 6 which is arranged between the first peristaltic pump 3 and a first waste collector 10, the dialysis fluid containers 4 and the draining line 6 may be alternatively connected to the supplying/draining line 7 by a valve 9 e.g. of electromechanical type.

20 The supplying/draining line 7 is provided with a Y-site 24 in order to connect a sampling line 8.

The peritoneal dialysis system according to figure 1 also include an automatic sampling system 2 made of a second peristaltic pump 11, a collection line 12, sampling containers 13 linked to the sampling line 8 via conduits 20 and a
25 analyzing line 16 comprising an analyzing unit 15. The sampling line 8, the conduits 20, the analyzing line 16 and the collection line 12 are all alternatively connected to the second peristaltic pump 11 by an appropriate valve 19.

The sampling containers 13 are arranged within a cooling container 14.

Both first system 1 and the automatic sampling system 2 may change information
30 via a communication line 18 (by cable or by wireless communication). The automatic sampling system 2 is provided with a memory key 25 which contains all the necessary data to program the functioning of said automatic peritoneal dialysis sampling system and to store the sampling information.

35 The automatic sampling system 2 can be programmed to take volumic fractions of liquid at predetermined times, for instance during the dwell time. Those volumic fractions may differ from each others.

- 5 The volumic fractions may also be taken during the drain cycle.
The collection line 12 allows to purge a dead volume between samplings.

10 Figure 2 shows another configuration, very similar to the configuration of figure 1, but which uses only one peristaltic pump 3 for supplying dialysis liquid to the patient, draining dialysis fluid from the patient and supplying volumic fractions to the automatic sampling system 2. In this configuration, the sampling line 8 is connected on the draining line 6. In said configuration, sampling are controlled by the peristaltic pump which may be activated for sampling purposes at any time, including during the dwell time.

15

Of course the invention is not limited to the above detailed embodiments. Generally it covers any automatic sampling system 2 which can take volumic fractions of liquid during a dwell cycle or a drain cycle.

20

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Claims

1. A peritoneal dialysis sampling system to be used together with a peritoneal dialysis system which is programmed to deliver fluid to a peritoneal cavity of a patient and to drain the fluid from the cavity, said peritoneal dialysis system comprising a supplying line and supplying means for supplying dialysis fluid to the peritoneal cavity, a draining line and draining means for draining the fluid from the cavity, said peritoneal dialysis sampling system being characterized by the fact that it consists of an automatic sampling system which is able to automatically sample volumic fractions of the dialysate contained in the peritoneum of the patient at specific time intervals in order to evaluate the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a given patient.
2. Automatic peritoneal dialysis sampling system according to claim 1 furthermore comprising means for defining the specific time intervals for sampling volumic fractions in relation with the peritoneal dialysis program sequences in order to better evaluate the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a given patient..
3. Automatic peritoneal dialysis sampling system according to any of the previous claims furthermore comprising means for allowing the use of different peritoneal dialysis liquids and/or different concentrations for each exchange cycle.
4. Automatic peritoneal dialysis sampling system according to any of the previous claims furthermore comprising connecting means for allowing a connection to a Y-site on the draining which is situated between the patient peritoneum and the draining means of the peritoneal dialysis system in order to collect samples at different intervals independently of the drain cycles.

- 5 5. Automatic peritoneal dialysis sampling system according to claim 4
furthermore comprising means for allowing the automatic sampling during
the dwell time of the peritoneal dialysis cycle and/or during the drain cycle in
order to improve the evaluation of the peritoneal membrane characteristics
and/or improve the peritoneal dialysis for a given patient..
- 10 6. Automatic peritoneal dialysis sampling system according to any of the claim
4 or 5 wherein it comprises a series of sampling containers, pumping
means and a series of valves in order to direct a certain quantity of each
fluid sample to a given sampling container.
- 15 7. Automatic peritoneal dialysis sampling system according to the previous
claim wherein said pumping means is of a peristaltic type.
- 20 8. Automatic peritoneal dialysis sampling system according to any of the claims
1 to 3 furthermore comprising connecting means for connecting it to the
draining line between the draining means and a waste collector in order to
collect samples of specific drain cycles.
- 25 9. Automatic peritoneal dialysis sampling system according to claim 8 wherein
the automatic peritoneal dialysis system is composed of a series of valves
which are controlled by an electronic system in order to direct a certain
quantity of each fluid sample to a specific sampling container.
- 30 10. Automatic peritoneal dialysis sampling system according to claim 9 wherein
the valves of such automatic peritoneal dialysis sampling system are
controlled by the automatic peritoneal dialysis system in order to open and
close at specific time intervals in relation with the peritoneal dialysis cycles.
- 35 11. Automatic peritoneal dialysis sampling system according to any of the claims
6 or 9, wherein the valves are of an electromagnetic type

- 5 12. Automatic peritoneal dialysis sampling system according to any of the previous claims furthermore comprising means for eliminating a volume of liquid between two samplings at least equivalent to the dead volume contained between the patient and the sampling level.
- 10 13. Peritoneal dialysis system including an automatic peritoneal dialysis sampling system according to any of the previous claims furthermore comprising an automatic peritoneal dialysis exchange system, both automatic peritoneal dialysis sampling system and automatic peritoneal dialysis exchange system being connected to the patient peritoneum and
15 comprising means for exchanging information together in order for the automatic peritoneal dialysis sampling system to determine the appropriate timing for each sampling on the basis of the dialysis exchange cycles of the automatic peritoneal dialysis exchange system.
- 20 14. Peritoneal dialysis sampling system according to the previous claim wherein both automatic peritoneal dialysis sampling system and automatic peritoneal dialysis exchange system are similar systems which are synchronized and which are working with different software and fluidic connections.
- 25 15. Automatic peritoneal dialysis sampling system according to any of the previous claims wherein it comprises a memory key which contains all the necessary data to program the functioning of said automatic peritoneal dialysis sampling system and to store the sampling information.
- 30 16. Automatic peritoneal dialysis sampling system according to any of the previous claims wherein sampling containers consist of soft pouches.
- 35 17. Automatic peritoneal dialysis sampling system according to any of the previous claims 1 to 15, wherein sampling containers consist of containers with vacuum in order to draw the liquid automatically when in open connection with the drawing line.

- 5 18. Automatic peritoneal dialysis sampling system according to any of the claims
1 to 15, furthermore comprising means for sequentially collecting sample
volumes in a tubing, each sample being separated from the previous one by
an air bubble inserted by the automatic peritoneal sampling system in-
between each sample.
- 10 19. Automatic peritoneal dialysis sampling system according to any of the
previous claims 6 to 18 wherein said sampling containers are enclosed
inside a cooling box which comprises cooling means to maintain the
samples in optimal condition for storage until analysis.
- 15 20. Automatic peritoneal dialysis sampling system according to any of the
previous claims wherein it comprises analyzing means for directly analyzing
of at least one characteristic of the sample in-line, such as by spectroscopy,
fluorometry or by use of chemical or electro-chemical means.
- 20 21. Automatic peritoneal dialysis sampling system according to the previous
claim wherein said analyzing means allow the measurement of at least one
of the following constituents or characteristics : glucose, urea, creatinine,
Sodium, Chloride, albumine, proteins, osmolarity or ph.
- 25 22. Method of use of the automatic peritoneal dialysis sampling system
according to any of the previous claims 20 or 21 wherein the result of the in-
line analysis is used to optimize the next peritoneal dialysis exchange cycle
or sampling intervals in order to improve the membrane characteristics
evaluation and/or improve the peritoneal dialysis for a given patient.
- 30 23. Method of use of the automatic peritoneal dialysis sampling system
according to any of the previous claims wherein the specific time intervals
for sampling volumic fractions are defined in relation with the peritoneal
dialysis program sequences in order to better evaluate the peritoneal
35 membrane characteristics and/or improve the peritoneal dialysis for a given
patient.

5

24. Method of use of the automatic peritoneal dialysis system according to any of the claims 1 to 22 wherein different peritoneal dialysis liquids and/or different concentrations are used for each exchange cycle, whether it is a tidal exchange or a full exchange cycle.

10

25. Method of use of the automatic peritoneal dialysis system according to any of the previous claims, wherein the automatic sampling occurs during the dwell time of the peritoneal dialysis cycle and/or during the drain cycle in order to improve the evaluation of the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a given patient.

15

26. Method of use of the automatic peritoneal dialysis system according to any of the claims 1 to 21 wherein a volume of liquid at least equivalent to the dead volume contained between the patient and the sampling level is eliminated between two samplings .

20

27. Method of use of the automatic peritoneal dialysis system according to any of the claims 1 to 15 and 18 to 21, wherein the sampling volumes are sequentially collected in a tubing; each sample being separated from the previous one by an air bubble inserted by the automatic peritoneal sampling system in-between each sample.

25

28. Method of use of the automatic peritoneal dialysis system according to any of the claims 1 to 21 wherein the samples are directly analyzed in-line, such as by spectrometric, fluorometric, electro-chemical or chemical means.

30

29. Method of use according to the previous claim wherein the result of the in-line analysis is used to optimize the next peritoneal dialysis exchange cycle or sampling intervals in order to improve the membrane characteristics evaluation and/or improve the peritoneal dialysis for a given patient.

35

FIG. 1

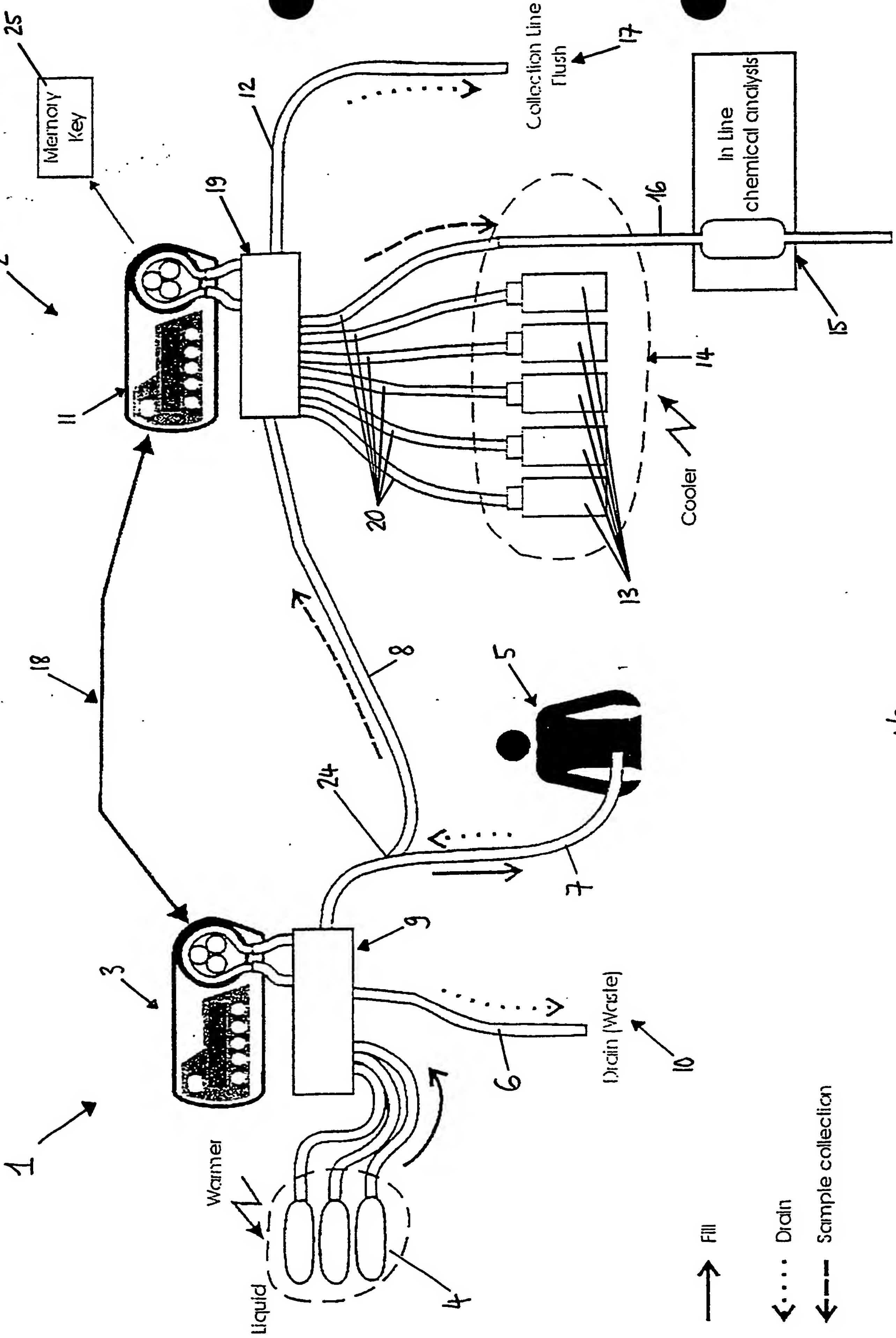
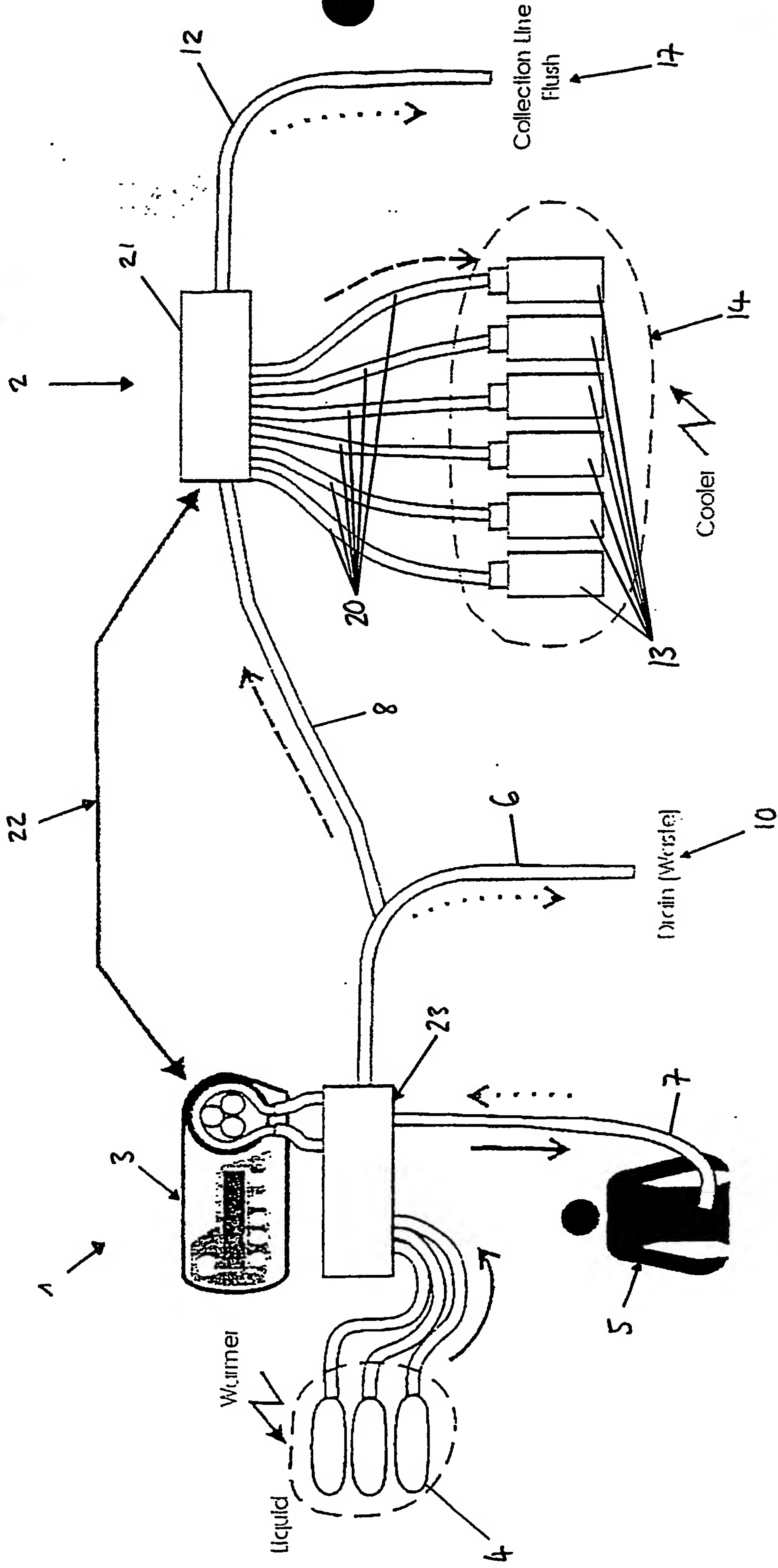


Fig. 2



2/2

———> Fill
 - - - -> Drain
 ·····> Sample collection